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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,163	05/11/2006	Deok-Hoon Park	DE1683	3283

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
08/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/579,163	PARK ET AL.	
	Examiner	Art Unit	
	GOLLAMUDI S. KISHORE	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 6-23-10 is acknowledged.

Claims included in the prosecution are 1, 3-4 and 6-11.

In view of the amendment, the 112 rejection is withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popp (US 2006/0029657) in combination with Foldvari (5,853,755), optionally in further combination with Needham (US 2002/0102298).

Popp discloses topical skin protectant compositions containing 0.05 to 5 % phospholipid (hydrogenated lecithin), 0.001 to about 1.5 % ceramide, 0.1 to 5 % squalane, 8 to 30 % triglyceride, 2 to 5 % phytosterol. Although Popp teaches the use of an essential fatty acid, the fatty acid is in the form of oil. The composition is prepared by heating the oil phase components at a temperature of 40-50 degrees, mixing with the aqueous phase at the same temperature and homogenizing the mixture at 3000 rpm (0030-0117; 0164; 0195-0210; examples and claims.). Since the method of preparation is the same, the presence of multilayered liposomes is implicit. What is lacking in Popp is the use of fatty acid as such.

Foldvari teaches multilamellar vesicles for topical delivery. The liposomes contain a phospholipid, a ceramide and fatty substances to enhance the strength of the lipid bilayers. These include cholesterol and fatty acids such as stearic acid (0.5 %). The compositions further include oil and an active agent. The hydrophilic solvents include ethanol. The method of preparation involves mixing the two phases together at 40 to 80 degrees and homogenizing the mixture (abstract, col. 4, lines 8-41; col. 5, line 1 through col. 7, line 3; col. 8, line 47 through col. 10, line 9; col. 11, line 1 through col. 12, line 35; Examples). What is lacking Foldvari is the inclusion of squalane.

To include a fatty acid in the compositions of Popp would have been obvious to one of ordinary skill in the art since Foldvari teaches that fatty acids enhance the strength of the lipid bilayers. Alternately, to include squalane in the compositions of Foldvari would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since Popp teaches that squalane is a therapeutic ingredient for the skin and its routine incorporation in topical formulations. The criticality of the sizes now recited is unclear to the examiner since the sizes of the multilamellar vesicles could be controlled by the speed of the mechanical vibration or homogenization. The examiner cites US 5,660,856 (see col. 5, lines 47-67), 5,965,156 (see col. 5, line 53 through col. 6, line 7) and 6,689,381 (see col. 9, lines 30-47) in this context. One of ordinary skill in the art would expect sizes of the liposomes in Popp and Foldvari to be similar to the claimed sizes since the reference of Needham indicates that the hydration of the phospholipid with an aqueous medium would result in multilamellar vesicles

having average sizes of 700 nm. It should be noted that according to instant specification, the sizes can between 200 to 5000 nm.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the disclosure of Popp is directed to a composition for skin protection and that Popp does not describe a liposome being produced from the components thereof and no data exists in the description of Popp to identify the production of liposome. According to applicant since Popp does not identify the production of a liposome, a method of preparing multilamellar liposomes cannot be implicit.

These arguments are not persuasive. It is well known in the art that multilamellar liposomes are produced when an amphiphilic lipid such as a phospholipid is hydrated or added with an aqueous medium which upon further sonication or high pressure homogenization convert into unilamellar vesicles or liposomes. The prior art submitted by applicant itself shows that liposomes are produced when amphiphilic lipid is combined with an aqueous medium ((JP 02-149336 and H08-509202).

Applicant argues that Foldvari is directed to biphasic multilamellar vesicles which need not be multilayered, whereas the present invention is directed solely to a multilayered liposome for transdermal absorption. According to applicant, multilayered liposome of the present invention is formed without the use of a high-pressure homogenizer as is conventional in the formation of a liposome. This argument is not persuasive since instant claim language does not exclude high-pressure homogenization or a biphasic nature of the multilamellar liposomes taught by Foldvari.

The examiner also points out that that the terms 'multilayered' and 'multilamellar' are used for the liposomes which have concentric layers of lipid bilayers. The examiner cites US 2004/0170678 in this context (see 0034).

Applicant argues that the formation of a multilayered liposome could not be identified in Fig. 1 of Foldvari and the existence of a multilayer liposome cannot be verified in Figs. 2 and 3. This argument is not persuasive since reference clearly refers to the liposomes as multilamellar and the multilamellar nature of the liposomes is clearly evident from Fig. 3 of Foldvari.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GOLLAMUDI S. KISHORE whose telephone number is

(571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK